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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,877	07/06/2001	Palle Schneider	10179.204-US	4404

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,877	Applicant(s) SCHNEIDER ET AL.	
	Examiner Elizabeth Slobodyansky, PhD	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46 and 48-85 is/are pending in the application.
- 4a) Of the above claim(s) 48,49,52-67,72-74,76 and 78-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46,50,51,68-71,75 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/8/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 8, 2006 has been entered.

The amendment filed May 8, 2006 amending claim 46, canceling claim 47 and adding claims 75-85 has been entered.

Claims 46 and 48-85 are pending. Claims 48, 49, 52-67 and 72-74 have been previously withdrawn.

Election/Restrictions

Newly submitted claims 76 and 78-85 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 76 and 78-85 correspond to non-elected species of Group I (Office action mailed May 19, 2004, pages 3-4; Office action mailed February 24, 2005, page 2).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 76 and 78-85 are withdrawn from

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consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 75 and 77 are rejoined as a generic claim and the claim reading on the elected species of substitution at position G121 in SEQ I NO:10, respectively.

Claims 46, 50, 51, 68-71, 75 and 77 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46, 50, 51 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 46 as amended is directed to a variant of a *Myceliophthora thermophila* laccase which comprises a substitution corresponding to at least one of the 10 specific positions in SEQ ID NO:10. Claims 50 and 51 depend from claim 46 and are drawn to a variant of a *Myceliophthora thermophila* laccase which comprises a substitution corresponding to position G121 in SEQ ID NO:10. Since "comprising" is open language, the number of allowed additional mutations is not limited. Furthermore, the specification does not define at what percent homology to SEQ ID NO:10 a variant laccase is

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considered a variant of a *Myceliophthora thermophilat* laccase versus just a variant laccase. The specific substitutions represent about 0.17%-1.7% of SEQ ID NO:10 that is 573 amino acid long. Therefore, said genus of variant laccases is characterized by laccase function only. Therefore, the genus of said variant laccases encompasses enzymes with structures with an unknown and possibly low homology to SEQ ID NO: 10 having different properties. While applicants disclose variants having the amino acid sequences that differ from SEQ ID NO:10 by substitutions at the indicated positions, the claimed genus is highly variable as it encompasses great number of undisclosed variants with undisclosed structures and properties. Moreover, the specification fails to describe any other representative species with changes in positions other than specifically indicated by any identifying characteristics or properties other than the "functionality" of being a laccase variant and fails to provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 68-71 are included in this rejection as dependent from claim 46.

Claims 46, 50, 51 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a variant of a *Myceliophthora thermophila* laccase having an amino acid sequence that differs from SEQ ID NO:10 by

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a substitution corresponding to at least one of the 10 specific positions therein, does not reasonably provide enablement for a variant of a *Myceliophthora thermophila* laccase having an amino acid sequence that comprises a substitution corresponding to at least one of the 10 specific positions wherein said variant amino acid sequence has an unknown homology to SEQ ID NO:10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731. 8 USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim 46, with dependent claims 68-71, is directed to a variant of a *Myceliophthora thermophila* laccase having an amino acid sequence comprising a substitution in SEQ ID NO:10 corresponding to at least one of the 10 specific positions of any structure and properties (the number of possible substitutions is not limited). Claims 50 and 51 are directed to a variant of a *Myceliophthora thermophila* laccase having an amino acid sequence comprising a specific substitution at position 121 in SEQ ID NO:10 of any structure and properties (the number of possible substitutions is not limited).

Claims 46, 50, 51 and 68-71 are so broad as to encompass any variant of a *Myceliophthora thermophila* laccase having an amino acid sequence comprising a substitution corresponding to at least one of the 10 specific positions in SEQ ID NO:10 with an unknown and possible low homology to the laccase of *Myceliophthora thermophila*. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of variant laccase enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of the variants having the substitutions at the specific positions in SEQ ID NO:10. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. The specification does not support the broad

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scope of the claims which encompass any variant laccase having an undisclosed homology to the laccase of *Myceliophthora thermophila* in which the amino acid corresponding to the specific positions in SEQ ID NO:10 is substituted because the specification does not establish: (A) regions of the protein structure which may be modified without effecting laccase activity, (B) the general tolerance of laccases to modification and extent of such tolerance, (C) a rational and predictable scheme for modifying any laccase residues with an expectation of retaining the desired biological function, and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications in laccase of *Myceliophthora thermophila* sequence in addition to the specific mutations recited in the claim. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making variant laccases is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears that the double recitation of "at least one" in claim 75 is redundant rendering the claim confusing. Claim 77 depends from claim 75 and is drawn to a variant with "at least one substitution at a position corresponding to position G121 in SEQ D NO:10". The claim is confusing since it can be only one substitution at a single position such as G121.

No art was found for the elected species of G121 (Office action mailed November 4, 2005, page 4).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46 and 75 are rejected under 35 U.S.C. 102(a), (e) as being anticipated by Pedersen et al.

Pedersen et al. (US Patent 5,998,353) teach a variant *Myceliophthora thermophila* laccase with a substitution at position W507 (column 6; column 20, especially Tables 3 and 4). They teach detergent compositions comprising a variant laccase (claims 2-5).

Claims 46 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen et al.

Pedersen et al. (WO 98/27197, form PTO-1449 7/6/01) teach a variant *Myceliophthora thermophila* laccase with a substitution at position W507 (page 4, line 28; page 5, line 3, claim 2). They teach detergent compositions comprising a variant laccase (claims 16-19).

Conclusion

This is a RCE of applicant's earlier Application No. 09/869,877. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

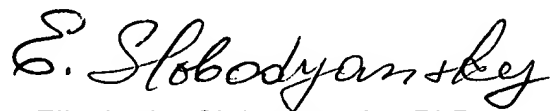
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

June 29, 2006